



DEC 31 2008

Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 5,250,542 was filed on June 17, 2008, under 35 U.S.C. § 156. Please note that Applicant has also applied for extension for U.S. Patent No. 5,434,171 for NDA No. 21-775 pursuant to the provisions of 37 C.F.R. § 1.785

The assistance of your Office is requested in confirming that the product identified in the application, ENTEREG® (alvimopan), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved.<sup>1</sup> Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

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<sup>1</sup>The filing of the application on June 17, 2008, was timely, given the NDA approval date of May 20, 2008. Applicant, however, misidentified at section 5 on page 5 of the application the last day the application may be submitted as July 19, 2008, pursuant to 37 C.F.R. § 1.740(a)(5). Under both 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), a PTE applicant has sixty days to submit a PTE application, with the first day of that sixty-day period beginning on the FDA approval date. The absolute deadline for filing the present PTE Application is thus July 18, 2008, or sixty days from May 20, 2008, starting the count of the sixty-day period on May 20, 2008. The Federal Circuit in *Unimed, Inc. v. Quigg*, 12 USPQ2d 1644, 1646, made clear that "section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date."

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).



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Mary C. Tyl

Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner

for Patent Examination Policy

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